

# Calendar No. 245

114TH CONGRESS  
1ST SESSION

# S. 481

To amend the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2015

Mr. HATCH (for himself, Mr. WHITEHOUSE, and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

OCTOBER 1, 2015

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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# A BILL

To amend the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1   **SECTION 1. SHORT TITLE.**

2       This Act may be cited as the “Improving Regulatory  
3       Transparency for New Medical Therapies Act”.

4   **SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW  
5                     FDA-APPROVED DRUGS.**

6       (a) **EFFECTIVE DATE OF APPROVAL.—**

7               (1) **EFFECTIVE DATE OF DRUG APPROVAL.—**  
8       Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at  
9       the end the following:

10      “(x) **DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.**—

11       “(1) **IN GENERAL.**—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

12       “(2) **DATE OF APPROVAL.**—For purposes of this section, with respect to an application described in paragraph (1), the term ‘date of approval’ shall mean the later of—

1               “(A) the date an application under sub-  
2               section (b) is approved under subsection (c); or  
3               “(B) the date of issuance of the interim  
4               final rule controlling the drug.”.

5               **(2) EFFECTIVE DATE OF APPROVAL OF BIO-**  
6               **LOGICAL PRODUCTS.**—Section 351 of the Public  
7               Health Service Act (42 U.S.C. 262) is amended by  
8               adding at the end the following:

9               “(n) **DATE OF APPROVAL IN THE CASE OF RE-**  
10               **COMMENDED CONTROLS UNDER THE CSA.**—

11               “(1) **IN GENERAL.**—In the case of an applica-  
12               tion under subsection (a) with respect to a biological  
13               product for which the Secretary provides notice to  
14               the sponsor that the Secretary intends to re-  
15               commend controls under the Controlled Substances  
16               Act, approval of such application shall not take ef-  
17               fect until the interim final rule controlling the bio-  
18               logical product is issued in accordance with section  
19               201(j) of the Controlled Substances Act.

20               “(2) **DATE OF APPROVAL.**—For purposes of  
21               this section, with respect to an application described  
22               in paragraph (1), references to the date of approval  
23               of such application, or licensure of the product sub-  
24               ject to such application, shall mean the later of—

1               “(A) the date an application is approved  
2               under subsection (a); or

3               “(B) the date of issuance of the interim  
4               final rule controlling the biological product.”.

5               **(3) EFFECTIVE DATE OF APPROVAL OF ANIMAL  
6 DRUGS.—**

7               **(A) IN GENERAL.**—Section 512 of the Fed-  
8               eral Food, Drug, and Cosmetic Act (21 U.S.C.  
9               360b) is amended by adding at the end the fol-  
10               lowing:

11               **“(q) DATE OF APPROVAL IN THE CASE OF RE-  
12 CMENDED CONTROLS UNDER THE CSA.—**

13               **“(1) IN GENERAL.**—In the case of an applica-  
14               tion under subsection (b) with respect to a drug for  
15               which the Secretary provides notice to the sponsor  
16               that the Secretary intends to recommend controls  
17               under the Controlled Substances Act, approval of  
18               such application shall not take effect until the in-  
19               terim final rule controlling the drug is issued in ac-  
20               cordance with section 201(j) of the Controlled Sub-  
21               stances Act.

22               **“(2) DATE OF APPROVAL.**—For purposes of  
23               this section, with respect to an application described  
24               in paragraph (1), the term ‘date of approval’ shall  
25               mean the later of—

1               “(A) the date an application under sub-  
2        section (b) is approved under subsection (c); or  
3               “(B) the date of issuance of the interim  
4        final rule controlling the drug.”.

5               (B) C<sub>O</sub>N<sub>D</sub>ITI<sub>O</sub>NAL A<sub>P</sub>P<sub>R</sub>O<sub>V</sub>AL.—Section  
6        571(d) of the Federal Food, Drug, and Cos-  
7        metic Act (~~21 U.S.C. 360eee(d)~~) is amended by  
8        adding at the end the following:

9               “(4)(A) In the case of an application under  
10      subsection (a) with respect to a drug for which the  
11      Secretary provides notice to the sponsor that the  
12      Secretary intends to recommend controls under the  
13      Controlled Substances Act, conditional approval of  
14      such application shall not take effect until the in-  
15      terim final rule controlling the drug is issued in ac-  
16      cordance with section 201(j) of the Controlled Sub-  
17      stances Act.

18               “(B) For purposes of this section, with respect  
19      to an application described in subparagraph (A), the  
20      term ‘date of approval’ shall mean the later of—

21               “(i) the date an application under sub-  
22        section (a) is conditionally approved under sub-  
23        section (b); or

24               “(ii) the date of issuance of the interim  
25        final rule controlling the drug.”.

1                             (C) INDEXING OF LEGALLY MARKETED  
2                             UNAPPROVED NEW ANIMAL DRUGS.—Section  
3                             572 of the Federal Food, Drug, and Cosmetic  
4                             Act (21 U.S.C. 360eee-1) is amended by add-  
5                             ing at the end the following:

6                 “(k) In the case of a request under subsection (d)  
7                     to add a drug to the index under subsection (a) with re-  
8                     spect to a drug for which the Secretary provides notice  
9                     to the person filing the request that the Secretary intends  
10                    to recommend controls under the Controlled Substances  
11                    Act, a determination to grant the request to add such drug  
12                    to the index shall not take effect, and the Secretary shall  
13                    not list the drug on such index, until the interim final rule  
14                    controlling the drug is issued in accordance with section  
15                    201(j) of the Controlled Substances Act.”.

16                             (4) DATE OF APPROVAL FOR DESIGNATED NEW  
17                             ANIMAL DRUGS.—Section 573(e) of the Federal  
18                             Food, Drug, and Cosmetic Act (21 U.S.C. 360eee-  
19                             2(e)) is amended by adding at the end the following:

20                 “(3) For purposes of determining the 7-year pe-  
21                     riod of exclusivity under paragraph (1) for a drug  
22                     for which the Secretary intends to recommend con-  
23                     trols under the Controlled Substances Act, the drug  
24                     shall not be considered approved or conditionally ap-  
25                     proved until the date that the interim final rule con-

1           trolling the drug is issued in accordance with section  
2           201(j) of the Controlled Substances Act.”.

3           **(b) SCHEDULING OF NEWLY APPROVED DRUGS.—**

4   Section 201 of the Controlled Substances Act (21 U.S.C.  
5   811) is amended by inserting after subsection (i) the fol-  
6   lowing:

7           “(j)(1) With respect to a drug referred to in sub-  
8   section (f), if the Secretary of Health and Human Services  
9   recommends that the Attorney General add the drug to  
10   schedule II, III, IV, or V pursuant to subsections (a) and  
11   (b), the Attorney General shall, not later than 90 days  
12   after the date described in paragraph (2), issue an interim  
13   final rule controlling the drug in accordance with such  
14   subsections and section 202(b) using the procedures de-  
15   scribed in paragraph (3).

16           “(2) The date described in this paragraph shall be  
17   the later of—

18           “(A) the date on which the Attorney General  
19   receives the scientific and medical evaluation and  
20   recommendations from the Secretary of Health and  
21   Human Services in accordance with subsection (b);  
22   or

23           “(B) the date on which the Attorney General  
24   receives notification from the Secretary of Health  
25   and Human Services that the Secretary has ap-

1 proved an application under section 505(c), 512,  
2 571, or 572 of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health  
3 Service Act with respect to the drug described in  
4 paragraph (1).

6 “(3) A rule issued by the Attorney General under  
7 paragraph (1) shall be in accordance with the procedures  
8 provided in subsection (a), except that the rule shall be-  
9 come immediately effective as an interim final rule without  
10 requiring the Attorney General to demonstrate good cause  
11 therefor. After publication of the interim final rule, the  
12 Attorney General shall issue a final rule in accordance  
13 with the procedures provided in subsection (a).”.

14 (e) EXTENSION OF PATENT TERM.—Section 156 of  
15 title 35, United States Code, is amended—

16 (1) in subsection (d)(1), in the matter pre-  
17 ceeding subparagraph (A), by inserting “, or in the  
18 case of a drug product described in subsection (i)  
19 within the sixty-day period beginning on the covered  
20 date (as defined in subsection (i))” after “marketing  
21 or use”; and

22 (2) by adding at the end the following:

23 “(i)(1) For purposes of this section, if the Secretary  
24 of Health and Human Services provides notice to the  
25 sponsor of an application or request for approval, condi-

1 tional approval, or indexing of a drug product for which  
2 the Secretary intends to recommend controls under the  
3 Controlled Substances Act, beginning on the covered date,  
4 the drug product shall be considered to—

5 “(A) have been approved; and

6 “(B) have permission for commercial marketing  
7 or use.

8 “(2) In this subsection, the term ‘covered date’ means  
9 the later of—

10 “(A) the date an application is approved—

11 “(i) under section 351(a)(2)(C) of the  
12 Public Health Service Act; or

13 “(ii) under section 505(b) or 512(e) of the  
14 Federal Food, Drug, and Cosmetic Act;

15 “(B) the date an application is conditionally ap-  
16 proved under section 571(b) of the Federal Food,  
17 Drug, and Cosmetic Act;

18 “(C) the date a request for indexing is granted  
19 under section 572(d) of the Federal Food, Drug,  
20 and Cosmetic Act; or

21 “(D) the date of issuance of the interim final  
22 rule controlling the drug under section 201(j) of the  
23 Controlled Substances Act.”.

1   **SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.**

2       Section 303 of the Controlled Substances Act (21  
3   U.S.C. 823) is amended by adding at the end the fol-  
4   lowing:

5           “(i)(1) For purposes of registration to manufacture  
6   a controlled substance under subsection (d) for use only  
7   in a clinical trial, the Attorney General shall register the  
8   applicant, or serve an order to show cause upon the appli-  
9   cant in accordance with section 304(e), not later than 180  
10   days after the date on which the application is accepted  
11   for filing.

12          “(2) For purposes of registration to manufacture a  
13   controlled substance under subsection (a) for use only in  
14   a clinical trial, the Attorney General shall, in accordance  
15   with the regulations issued by the Attorney General, issue  
16   a notice of application not later than 90 days after the  
17   application is accepted for filing. Not later than 90 days  
18   after the date on which the period for comment pursuant  
19   to such notice ends, the Attorney General shall register  
20   the applicant, or serve an order to show cause upon the  
21   applicant in accordance with section 304(e), unless the At-  
22   torney General has granted a hearing on the application  
23   under section 1008(i) of the Controlled Substances Import  
24   and Export Act.”.

1 **SECTION 1. SHORT TITLE.**

2       *This Act may be cited as the “Improving Regulatory  
3 Transparency for New Medical Therapies Act”.*

4 **SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW  
5                     FDA-APPROVED DRUGS.**

6       (a) *EFFECTIVE DATE OF APPROVAL.—*

7               (1) *EFFECTIVE DATE OF DRUG APPROVAL.—Section  
8                     505 of the Federal Food, Drug, and Cosmetic Act  
9                     (21 U.S.C. 355) is amended by adding at the end the  
10                  following:*

11       “(x) *DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.*—

13               “(1) *IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.*

22               “(2) *DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term ‘date of approval’ shall mean the later of—*

1               “(A) the date an application under sub-  
2               section (b) is approved under subsection (c); or  
3               “(B) the date of issuance of the interim  
4               final rule controlling the drug.”.

5               (2) *EFFECTIVE DATE OF APPROVAL OF BIOLOGI-*  
6               *CAL PRODUCTS.*—Section 351 of the Public Health  
7               Service Act (42 U.S.C. 262) is amended by adding at  
8               the end the following:

9               “(n) *DATE OF APPROVAL IN THE CASE OF REC-*  
10               *OMMENDED CONTROLS UNDER THE CSA.*—

11               “(1) *IN GENERAL.*—In the case of an application  
12               under subsection (a) with respect to a biological prod-  
13               uct for which the Secretary provides notice to the  
14               sponsor that the Secretary intends to issue a scientific  
15               and medical evaluation and recommend controls  
16               under the Controlled Substances Act, approval of such  
17               application shall not take effect until the interim  
18               final rule controlling the biological product is issued  
19               in accordance with section 201(j) of the Controlled  
20               Substances Act.

21               “(2) *DATE OF APPROVAL.*—For purposes of this  
22               section, with respect to an application described in  
23               paragraph (1), references to the date of approval of  
24               such application, or licensure of the product subject to  
25               such application, shall mean the later of—

1               “(A) the date an application is approved  
2               under subsection (a); or

3               “(B) the date of issuance of the interim  
4               final rule controlling the biological product.”.

5               (3) **EFFECTIVE DATE OF APPROVAL OF ANIMAL  
6 DRUGS.—**

7               (A) **IN GENERAL.**—Section 512 of the Fed-  
8               eral Food, Drug, and Cosmetic Act (21 U.S.C.  
9               360b) is amended by adding at the end the fol-  
10               lowing:

11               “(q) **DATE OF APPROVAL IN THE CASE OF REC-  
12 OMMENDED CONTROLS UNDER THE CSA.**—

13               “(1) **IN GENERAL.**—In the case of an application  
14               under subsection (b) with respect to a drug for which  
15               the Secretary provides notice to the sponsor that the  
16               Secretary intends to issue a scientific and medical  
17               evaluation and recommend controls under the Con-  
18               trolled Substances Act, approval of such application  
19               shall not take effect until the interim final rule con-  
20               trolling the drug is issued in accordance with section  
21               201(j) of the Controlled Substances Act.

22               “(2) **DATE OF APPROVAL.**—For purposes of this  
23               section, with respect to an application described in  
24               paragraph (1), the term ‘date of approval’ shall mean  
25               the later of—

1               “(A) the date an application under sub-  
2       section (b) is approved under subsection (c); or  
3               “(B) the date of issuance of the interim  
4       final rule controlling the drug.”.

5               (B) *CONDITIONAL APPROVAL*.—Section  
6       571(d) of the Federal Food, Drug, and Cosmetic  
7       Act (21 U.S.C. 360ccc(d)) is amended by adding  
8       at the end the following:

9               “(4)(A) In the case of an application under sub-  
10      section (a) with respect to a drug for which the Sec-  
11      retary provides notice to the sponsor that the Sec-  
12      retary intends to issue a scientific and medical eval-  
13      uation and recommend controls under the Controlled  
14      Substances Act, conditional approval of such applica-  
15      tion shall not take effect until the interim final rule  
16      controlling the drug is issued in accordance with sec-  
17      tion 201(j) of the Controlled Substances Act.

18               “(B) For purposes of this section, with respect to  
19      an application described in subparagraph (A), the  
20      term ‘date of approval’ shall mean the later of—

21               “(i) the date an application under sub-  
22      section (a) is conditionally approved under sub-  
23      section (b); or

24               “(ii) the date of issuance of the interim  
25      final rule controlling the drug.”.

1                   (C) INDEXING OF LEGALLY MARKETED UN-  
2                   APPROVED NEW ANIMAL DRUGS.—Section 572 of  
3                   the Federal Food, Drug, and Cosmetic Act (21  
4                   U.S.C. 360ccc–1) is amended by adding at the  
5                   end the following:

6                 “(k) In the case of a request under subsection (d) to  
7                 add a drug to the index under subsection (a) with respect  
8                 to a drug for which the Secretary provides notice to the  
9                 person filing the request that the Secretary intends to issue  
10                a scientific and medical evaluation and recommend controls  
11                under the Controlled Substances Act, a determination to  
12                grant the request to add such drug to the index shall not  
13                take effect until the interim final rule controlling the drug  
14                is issued in accordance with section 201(j) of the Controlled  
15                Substances Act.”.

16                (4) DATE OF APPROVAL FOR DESIGNATED NEW  
17                ANIMAL DRUGS.—Section 573(c) of the Federal Food,  
18                Drug, and Cosmetic Act (21 U.S.C. 360ccc–2(c)) is  
19                amended by adding at the end the following:

20                “(3) For purposes of determining the 7-year pe-  
21                riod of exclusivity under paragraph (1) for a drug for  
22                which the Secretary intends to issue a scientific and  
23                medical evaluation and recommend controls under the  
24                Controlled Substances Act, the drug shall not be con-  
25                sidered approved or conditionally approved until the

1       *date that the interim final rule controlling the drug*  
2       *is issued in accordance with section 201(j) of the Con-*  
3       *trolled Substances Act.”.*

4       *(b) SCHEDULING OF NEWLY APPROVED DRUGS.—Sec-*  
5       *tion 201 of the Controlled Substances Act (21 U.S.C. 811)*  
6       *is amended by inserting after subsection (i) the following:*

7           “*(j)(1) With respect to a drug referred to in subsection*  
8       *(f), if the Secretary of Health and Human Services rec-*  
9       *ommends that the Attorney General control the drug in*  
10      *schedule II, III, IV, or V pursuant to subsections (a) and*  
11      *(b), the Attorney General shall, not later than 90 days after*  
12      *the date described in paragraph (2), issue an interim final*  
13      *rule controlling the drug in accordance with such sub-*  
14      *sections and section 202(b) using the procedures described*  
15      *in paragraph (3).*

16           “*(2) The date described in this paragraph shall be the*  
17      *later of—*

18           “*(A) the date on which the Attorney General re-*  
19       *ceives the scientific and medical evaluation and the*  
20       *scheduling recommendation from the Secretary of*  
21       *Health and Human Services in accordance with sub-*  
22       *section (b); or*

23           “*(B) the date on which the Attorney General re-*  
24       *ceives notification from the Secretary of Health and*  
25       *Human Services that the Secretary has approved an*

1       application under section 505(c), 512, or 571 of the  
2       Federal Food, Drug, and Cosmetic Act or section  
3       351(a) of the Public Health Service Act, or indexed  
4       a drug under section 572 of the Federal Food, Drug,  
5       and Cosmetic Act, with respect to the drug described  
6       in paragraph (1).

7       “(3) A rule issued by the Attorney General under para-  
8 graph (1) shall become immediately effective as an interim  
9 final rule without requiring the Attorney General to dem-  
10 onstrate good cause therefor. The interim final rule shall  
11 give interested persons the opportunity to comment and to  
12 request a hearing. After the conclusion of such proceedings,  
13 the Attorney General shall issue a final rule in accordance  
14 with the scheduling criteria of subsections (b), (c), and (d)  
15 of this section and section 202(b).”.

16       (c) EXTENSION OF PATENT TERM.—Section 156 of  
17 title 35, United States Code, is amended—

18               (1) in subsection (d)(1), in the matter preceding  
19 subparagraph (A), by inserting “, or in the case of a  
20 drug product described in subsection (i), within the  
21 sixty-day period beginning on the covered date (as de-  
22 fined in subsection (i))” after “marketing or use”;  
23 and

24               (2) by adding at the end the following:

1       “(i)(1) For purposes of this section, if the Secretary  
2 of Health and Human Services provides notice to the spon-  
3 sor of an application or request for approval, conditional  
4 approval, or indexing of a drug product for which the Sec-  
5 retary intends to recommend controls under the Controlled  
6 Substances Act, beginning on the covered date, the drug  
7 product shall be considered to—

8           “(A) have been approved or indexed under the  
9 relevant provision of the Public Health Service Act or  
10 Federal Food, Drug, and Cosmetic Act; and

11           “(B) have permission for commercial marketing  
12 or use.

13       “(2) In this subsection, the term ‘covered date’ means  
14 the later of—

15           “(A) the date an application is approved—

16              “(i) under section 351(a)(2)(C) of the Pub-  
17 lic Health Service Act; or

18              “(ii) under section 505(b) or 512(c) of the  
19 Federal Food, Drug, and Cosmetic Act;

20           “(B) the date an application is conditionally ap-  
21 proved under section 571(b) of the Federal Food,  
22 Drug, and Cosmetic Act;

23           “(C) the date a request for indexing is granted  
24 under section 572(d) of the Federal Food, Drug, and  
25 Cosmetic Act; or

1           “(D) the date of issuance of the interim final  
2         rule controlling the drug under section 201(j) of the  
3         Controlled Substances Act.”.

4 **SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.**

5         Section 303 of the Controlled Substances Act (21  
6 U.S.C. 823) is amended by adding at the end the following:

7           “(i)(1) For purposes of registration to manufacture a  
8 controlled substance under subsection (d) for use only in  
9 a clinical trial, the Attorney General shall register the ap-  
10 plicant, or serve an order to show cause upon the applicant  
11 in accordance with section 304(c), not later than 180 days  
12 after the date on which the application is accepted for fil-  
13 ing.

14           “(2) For purposes of registration to manufacture a  
15 controlled substance under subsection (a) for use only in  
16 a clinical trial, the Attorney General shall, in accordance  
17 with the regulations issued by the Attorney General, issue  
18 a notice of application not later than 90 days after the ap-  
19 plication is accepted for filing. Not later than 90 days after  
20 the date on which the period for comment pursuant to such  
21 notice ends, the Attorney General shall register the appli-  
22 cant, or serve an order to show cause upon the applicant  
23 in accordance with section 304(c), unless the Attorney Gen-  
24 eral has granted a hearing on the application under section

1 1008(i) of the Controlled Substances Import and Export  
2 Act.”.

3 **SEC. 4. RE-EXPORTATION AMONG MEMBERS OF THE EURO-**  
4 **PEAN ECONOMIC AREA.**

5 Section 1003 of the Controlled Substances Import and  
6 Export Act (21 U.S.C. 953) is amended—

7 (1) in subsection(f)—

8 (A) in paragraph (5)—

9 (i) by striking “(5)” and inserting  
10 “(5)(A);

11 (ii) by inserting “, except that the con-  
12 trolled substance may be exported from a  
13 second country that is a member of the Eu-  
14 ropean Economic Area to another country  
15 that is a member of the European Economic  
16 Area, provided that the first country is also  
17 a member of the European Economic Area”  
18 before the period at the end; and

19 (iii) by adding at the end the fol-  
20 lowing:

21 “(B) Subsequent to any re-exportation described  
22 in subparagraph (A), a controlled substance may con-  
23 tinue to be exported from any country that is a mem-  
24 ber of the European Economic Area to any other such  
25 country, if—

1           “(i) the conditions applicable with respect  
2       to the first country under paragraphs (1), (2),  
3       (3), (4), (6), and (7) are met by each subsequent  
4       country from which the controlled substance is  
5       exported pursuant to this paragraph; and

6           “(ii) the conditions applicable with respect  
7       to the second country under paragraphs (1), (2),  
8       (3), (4), (6), and (7) are met by each subsequent  
9       country to which the controlled substance is ex-  
10      ported pursuant to this paragraph.”; and

11       (B) in paragraph (6)—

12           (i) by striking “(6)” and inserting  
13       “(6)(A)”;  
and

14           (ii) by adding at the end the following:  
15       “(B) In the case of re-exportation among mem-  
16      bers of the European Economic Area, within 30 days  
17      after each re-exportation, the person who exported the  
18      controlled substance from the United States delivers to  
19      the Attorney General—

20           “(i) documentation certifying that such re-  
21      exportation has occurred; and

22           “(ii) information concerning the consignee,  
23      country, and product.”; and

24       (2) by adding at the end the following:

1       “(g) *LIMITATION.*—Subject to paragraphs (5) and (6)  
2 of subsection (f) in the case of any controlled substance in  
3 schedule I or II or any narcotic drug in schedule III or  
4 IV, the Attorney General shall not promulgate nor enforce  
5 any regulation, subregulatory guidance, or enforcement pol-  
6 icy which impedes re-exportation of any controlled sub-  
7 stance among European Economic Area countries, includ-  
8 ing by promulgating or enforcing any requirement that—  
9           “(1) re-exportation from the first country to the  
10 second country or re-exportation from the second  
11 country to another country occur within a specified  
12 period of time; or  
13           “(2) information concerning the consignee, coun-  
14 try, and product be provided prior to exportation of  
15 the controlled substance from the United States or  
16 prior to each re-exportation among members of the  
17 European Economic Area.”.



**Calendar No. 245**

114<sup>th</sup> CONGRESS  
1<sup>st</sup> SESSION

**S. 481**

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**A BILL**

To amend the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, and for other purposes.

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OCTOBER 1, 2015

Reported with an amendment